

VIA E-MAIL ONLY
(AC90.comments@uspto.gov)

U.S. Patent and Trademark Office
Mail Stop Comments-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attn: James Engel, Senior Legal Advisor

Re: GlaxoSmithKline's Comments on Proposed Rules to Require Identification of Attributable Owner

To Whom It May Concern:

GlaxoSmithKline LLC ("GSK") respectfully requests that the United States Patent and Trademark Office ("Office") consider the following comments in response to its Changes to Require Identification of Attributable Owner published in the Federal Register on January 24, 2014. GSK appreciates the opportunity to submit comments on the proposed rules and hopes that comments like these from the user community will assist the Office in modifying the rules to align any benefits that can be gained with the cost of doing so.

GSK offers comments below regarding how the burden estimate provided in the Notice does not meet legal and regulatory requirements. GSK also explains how the office has not specifically identified why voluntarily recording assignments is not adequate. GSK believes it is unclear what is meant by "an entity necessary to be joined in a lawsuit in order to have standing to enforce the patent or any patent resulting from the application" and describes why the attributable owner should be limited to the titleholder as set forth in a recorded assignment. GSK explains why the times for identifying attributable owner should be limited to filing, issuance, and the start of post grant proceedings. GSK provides comments regarding the recommended procedure for identifying the titleholder and the information required to identify a corporate titleholder. GSK also describes how the penalty for non-compliance is unclear in some instances.

I. The Burden Estimate Provided in the Notice Does Not Meet Legal and Regulatory Requirements

a. The Burden Estimate Provided in the Notice is Not “Objectively Supported”

The Paperwork Reduction Act (44 USC 3501 et seq.) and its implementing rules (5 CFR Part 1320) specify detailed procedures agencies must follow when creating or maintaining paperwork burdens on the public. Among other things, agencies are required to prepare and include within their requests for public comment “specific, objectively supported estimate of burden.” A “specific estimate” is one that is reported with a reasonable degree of precision. An “objectively supported” estimate is one that is based on facts, data, and/or the analysis thereof using credible and appropriate statistical techniques.

The estimates in the Notice appear to meet the “specific estimate” prong. For example the Office estimates that 1,116,100 responses identifying an attributable owner will be filed annually and that it will take an average of 6 minutes to gather the necessary information, create the document, and submit the completed request to the Office. These are specific numbers.

However, the estimate in the Notice is not “objectively supported.” The Notice states that the basis for the estimated annual reporting burdens can be found at the OMB’s ICR Web site www.reginfo.gov/public/do/PRAMain. GSK has reviewed the ICR – OIRA information for OMB Control No. 0651-0076 and the accompanying Supporting Statement dated December 12, 2013. Section 12 of the Supporting Statement appears to attempt to provide the basis for the burden hour calculation factors. Section 12 states:

The USPTO estimates that it will take the public, on average, approximately 6 minutes (0.1 hour) to identify the attributable owner in an application or patent and approximately 1 hour to correct a good faith failure to notify the Office of a change to the attributable owner (or to correct a good faith but *incorrect or incomplete indication of attributable owner*). This includes the time to gather the necessary information, create the document, and submit the completed request to the USPTO. The USPTO calculates that, on balance, it takes the same amount of time to gather the necessary information, create the document, and submit it to the USPTO, whether the public submits the information in paper form or electronically.

These estimates are based on the Agency’s long-standing institutional knowledge of and experience with the type of information collected and the

length of time necessary to complete responses containing similar or like information.

(emphasis added)

The basis given for the Office's estimate is its "long-standing institutional knowledge of and experience with the type of information collected and the length of time necessary to complete responses containing similar or like information." This conclusory statement does not provide objective support for the Office's estimates. For example, it does not provide the public with an explanation of how the estimate was derived including what statistical methods, if any, were used. This makes informed public comment extremely difficult.

Objectively supported burden estimates are required by law and are not optional for the Office. Without objectively supported burden estimates, this notice violates the legal and regulatory requirement to provide at least 60 days for the public to "[e]valuate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used." 5 U.S.C. 1320.8(d)(1)(ii).

b. The Burden Estimate in the Notice is Not "Transparent" and "Reproducible"

"Transparency" and "reproducibility" are minimum procedural requirements in OMB's government-wide and the Office's agency-specific Information Quality Guidelines.¹ The absence of objectively supported burden estimates means that this Notice is neither transparent nor reproducible and thus does not comply with these requirements.

c. The Office's Estimate of Its "Burden" Indicates that the Office Likely Grossly Underestimated the Burden to Applicants and Patentees

In the same Supporting Statement, Section 14, when describing the annual cost to the Federal Government of the proposed rules, the Office estimated that it would take a GS-7, step 1, employee approximately **18 minutes** on average to process the forms submitted by applicants and patentees. So, in an area where the Office has considerable expertise, the Office estimates it will take 18 minutes to process the form submitted by the applicant or patentee, but in an area where the Office likely has little knowledge and expertise, namely determining attributable

¹ OMB Information Quality Guidelines, p. 8460; U.S. Patent and Trademark Office, *Information Quality Guidelines*, <http://www.uspto.gov/products/cis/infoqualityguide.jsp>.

owners within a modern corporation including identifying the individual or group within the corporation in possession of the owner information, communicating with that individual including any needed follow-up, analyzing the retrieved information in the context of the patent filing, communicating the retrieved information to the patent paralegal who prepares the required form(s) and uploads them to EFS, communicating the filing to the formalities group, and updating docketing and electronic document storage systems, the Office estimates that it will take 6 minutes. It seems readily apparent from even this rudimentary analysis that it is likely the Office grossly underestimated the burden to applicants and patentees.

d. If the Burden Were Accurately Estimated, the Proposed Rules Would Likely Be “Economically Significant” and Require a Detailed Cost-Benefit Analysis under Section 6(a)(3)(C) of Executive Order 12866

As described above, the lack of objective support, transparency and reproducibility found in the Office’s burden estimate makes it extremely difficult if not impossible to make a reasoned analysis of the estimate. That said, if one assumes that the time required by applicants and patentees to perform the requisite attributable owner analysis, and to complete and submit the forms is equivalent to the time required by Office personnel to process them, namely 18 minutes, and assumes that all of the Office’s other estimates are correct, namely 1,116,100 responses filed annually and a professional rate of \$389/hour, the annual burden would be over \$120 million thereby exceeding the \$100 million threshold and making this an economically significant rule requiring a detailed cost-benefit analysis under section 6(a)(3)(C) of E.O. 12866. And GSK believes that the burden would certainly be far greater than the exemplified 18 minutes for large multinational corporations with complex legal infrastructures and large patent portfolios, which would push the burden well beyond even \$120 million.

e. Conclusion

In view of the shortcomings of the burden estimate provided in the Notice described above, GSK requests the Office to reissue the Notice of proposed rulemaking with a burden estimate that meets all of the legal and regulatory requirements and to reset the 60-day period for comment.

II. The Office Has Not Specifically Identified Why Voluntarily Recording Assignments Is Not Adequate

a. The Office Fails to Adequately Explain How the Proposed Rules Would Address the Five Primary Justifications Given

The Notice provides five primary justifications for implementing the proposed rules as discussed below. The Office fails to adequately explain how the proposed rules would address these five primary justifications.

- i. The Office asserts that identifying attributable owners will help ensure that a “power of attorney” is current in each application or proceeding before the Office. A legal representative of the applicant must have authority to represent the inventor or be in violation of the ethical rules, however, and generally, a power of attorney is present in the file to evidence this. The Office has not represented that fraudulent representation has been a problem with the current system for examining applications. Accordingly, this appears to be an insufficient rationale supporting the rules.
- ii. The Office asserts that identifying attributable owners will help avoid potential conflicts of interest for Office personnel. The Office has presented no evidence indicating that the current system has led to conflicts of interest in examination of applications, so that it is unclear if this is, in fact, a sufficient objective to impose the burden.
- iii. The Office asserts that identifying attributable owners will help determine the scope of prior art under the common ownership exception under 35 U.S.C. § 102(b)(2)(C) and uncover instances of double patenting. The prior art exception for applications commonly owned at the time the invention was made must be proved by the applicant – it is not the Office's responsibility to assume common ownership.

As for double patenting, it is the responsibility of the Office to make a suitable rejection treating the patent as third party prior art for obviousness in the absence of proof of common ownership. If the rejection is overcome on this basis, double patenting is not a problem. If it is apparent on the face of the patent application (e.g., such as in a continuation or continuation-in-part), then a rejection may be overcome by filing a terminal disclaimer. The filing of a

terminal disclaimer when the applications/patents are not commonly owned would be a violation of the ethical rules. Splitting ownership after the filing of a terminal disclaimer would result in violation of the terms of the terminal disclaimer. It is the applicant that proceeds at its own risk by not complying with the disclosure of proper ownership in applications and patents.

- iv. The Office asserts that identifying attributable owners will help to verify that the party making a request for a post-issuance proceeding is a proper party for the proceeding. Post-grant proceedings already have real party-in-interest disclosure requirements for the petitioner and such disclosure should be sufficient to reveal any common ownership issues with the patentee. As to supplemental examination, it already requires identification of the patent owner (37 C.F.R. § 1.610). Ex parte examination does not suffer from the issue of an improper petitioner or patentee, because it may be brought by any party, even a secret party, and there is no estoppel associated with the petitioner. Moreover, the ex parte reexamination must be defended by the patent owner.
- v. The Office asserts that identifying attributable owners will help ensure that the information the Office provides to the public concerning published applications and issued patents is accurate and not misleading. The Office has not provided any information leading to the conclusion that they are providing inaccurate information to the public regarding patent ownership. To the extent that this is a problem, the Office should examine the rate at which reported information is inaccurate and the impact of those inaccuracies to determine whether the benefit to the public outweighs the burdens imposed by the new rules.

The circumstances underlying each of these justifications have been in existence for several, if not many, years prior to this Notice. The Office has provided no rationale to explain why this rule is needed now.

b. The Office's Analysis of Assignments Filed in Pending Applications Suggests Voluntarily Recording Assignments is Adequate

In fact, the Office's analysis of the number of attributable owner submissions that may be required for pending applications indicates that the Office believes the current system of

voluntary disclosure of assignee information is adequate for identifying titleholder information.

In the Notice, at p. 4115, col. 3, the Office notes that:

about ninety-two percent of applications have recorded assignment documents at the time of patent grant, but fewer than four percent of applications have a second recorded assignment document each year reflecting some type of ownership transfer during the pendency of a patent application. The high percentage of patent applicants who currently submit an assignment document for recordation and the relatively low percentage of patent applicants who currently submit a second assignment document for recordation leads to the inference that changes in ownership during the pendency of a patent application are relatively infrequent (e.g., changes in ownership will occur in fewer than four percent of applications each year).

In drawing the inference from this data that changes in ownership will occur in fewer than four percent of applications each year, the Office appears to assume that patent applicants already record assignments each time there is a change in ownership. If patent applicants already record assignments each time there is a change in ownership, the current system of voluntarily recording assignments is adequate for identifying titleholder information.

If, on the other hand, the Office is attempting to imply that the proposed rules are needed because patent applicants are not recording assignments each time there is a change in ownership, the Office must perform a reanalysis to determine the number of additional submissions that will be necessitated by the rule change and include these additional submissions in the Office's burden estimate.

III. It is Unclear What is Meant by "An entity necessary to be joined in a lawsuit in order to have standing to enforce the patent or any patent resulting from the application"

Under the proposed rules, the attributable owner of a patent or application includes the following entities: (2) An entity necessary to be joined in a lawsuit in order to have standing to enforce the patent or any patent resulting from the application. It is unclear what is meant by this proposed requirement.

As a multi-national corporation, GSK has a corporate structure comprised of numerous legal entities, with various intra-company agreements among these entities governing patent ownership, exclusive license rights, and non-exclusive license rights. Exclusive licenses may be granted to different entities for different rights, such as the right to manufacture and the right

to sell/distribute. Through these intra-company agreements, some of the entities are beneficial patent owners, meaning that they are entitled to the profits derived from the patent. In certain instances, such beneficial patent owners may need to be joined in a patent infringement suit in order to collect damages. However, they may not need to be named in order to bring an infringement suit in which only an injunction is sought. It is unclear from the rules whether such beneficial owners would be considered to be attributable owners. To the extent that intra-company transfers of rights require reporting, the Office's assessment of the burden estimate required under the Paperwork Reduction Act is woefully unsupported.

IV. The Attributable Owner Should be Limited to the Titleholder as Set Forth in a Recorded Assignment

Under the proposed rules, the attributable owner of a patent or application includes each of the following entities:

- 1) An entity that, exclusively or jointly, has been assigned title to the patent or application; and
- 2) An entity necessary to be joined in a lawsuit in order to have standing to enforce the patent or any patent resulting from the application; and
- 3) The ultimate parent entity as defined in 16 CFR 801.1(a)(3) of an entity described in paragraphs 1) and 2) above; and
- 4) Any entity that, directly or indirectly, creates or uses a trust, proxy, power of attorney, pooling arrangement, or any other contract, arrangement, or device with the purpose or effect of temporarily divesting such entity of attributable ownership of a patent application, or preventing the vesting of such attributable ownership of a patent or application.

The precise scope of these categories is not readily discernible. To the extent that one is able to determine the scope of entities that would fall into these categories, GSK believes it would be an undue burden to determine on an ongoing basis all of the entities in categories 2 through 4. Identifying the titleholder, or legal owner, of the application or patent should be adequate to address the Office's concerns. In any case, the titleholder or ultimate parent entity should be able to address all issues of ownership transfer and licensed rights upon reasonable inquiry.

As described above in Section III, GSK has a corporate structure comprised of numerous legal entities, with various intra-company agreements among these entities governing patent

ownership and license rights. These intra-company agreements are entered into and administered by personnel from other departments, and thus, without investigation which can often be quite time-consuming, the patent attorney may not be aware of the precise nature of the agreements. Moreover, once the agreements that may be applicable are identified, an analysis would need to be performed to determine if the agreements relate to a given patent application or patent. In some circumstances this can be challenging as, for example, when the agreement has been drafted with reference to particular research programs rather than with reference to specific patents or patent applications, in which case the patent attorney must determine whether a given patent application or patent relates to the recited research program and is thus covered by the agreement. It should also be noted that an analysis of multiple agreements may be required to determine which, if any, make reference to the patent application or patent of interest. Once the one or more relevant agreements have been identified, a careful legal analysis of each agreement would be required to establish the status of the entities relative to the reporting requirements. It would be an undue burden to determine all such owners or similar owners to meet the attributable owner reporting requirements.

An additional reason that disclosing the entities in category 2 would pose an undue burden is the fact that GSK enforces only a small percentage of the patents that it obtains. Accordingly, it is only in a few limited circumstances where GSK currently has to determine the enforcement entities described in category 2. It would be an undue burden to be required to determine these entities not only in every granted patent regardless of whether it is to be enforced, but also in every patent application, many of which may never actually mature into a granted patent that could be enforced or licensed.

V. Times for Identifying Attributable Owner Should be Limited to Filing and, Issuance, and Start of Post Grant Proceedings

The proposed rules would require the attributable owner to be identified at:

- 1) Filing
- 2) If attributable ownership changes during prosecution
- 3) Issuance
- 4) Each maintenance fee
- 5) Start of Post Grant Proceedings

It would be adequate to identify the attributable owner at filing and upon payment of the Issue Fee. GSK routinely submits assignee information at filing and updates it as necessary upon payment of the Issue Fee. Assuming the attributable owner is limited to the titleholder, the proposed rules present no additional burden to reasonable patent practice. Regarding post-grant proceedings, it is GSK's understanding that some, if not all, of the post-grant proceedings require identification of the real party in interest. Accordingly disclosure of the attributable owner at this time should be feasible and reasonable.

a. It Will Pose an Undue Burden to Report Attributable Owner During Prosecution

It will pose an undue burden to require disclosure of the attributable owner during prosecution. The proposed rules would require disclosure of the attributable owner during prosecution within 3 months of a change of attributable ownership. GSK's corporate structure is similar that of many multi-national corporations and includes numerous legal entities. Changes in attributable owner, particularly as broadly as it is defined in the proposed rules, can be made by individuals and groups in the corporation without the knowledge of the patent attorney.

It is not feasible to expect patent attorneys practicing in a corporation of any substantial size or complexity, or outside counsel advising such a corporation for that matter, to stay informed of changes in attributable ownership during the course of patent prosecution so that the proper forms can be submitted to the Office within three months of a change. In order to do so, the patent attorney would have to routinely query the other individuals, groups, or departments who may have knowledge of attributable ownership in order to determine whether there has been a change. To avoid missing the three month window, the patent attorney would have to pose the query at least every 2-2 ½ months, for the life of the application. Assuming a 36 month prosecution, with the Notice of Allowance mailed at 33 months, the patent attorney would need to pose the query 13 times. And that is only for a single application. Multiply that by the number of applications on a practicing attorney's docket, and it becomes clear why this requirement would be unrealistic.

On the topic of burden, the Office mistakenly believes that only submissions pose a burden for the applicant and patentee. That is simply not correct. The applicant or patentee has to obtain the necessary information and perform the analysis to determine if there has been a change in attributable owner *even if* it is ultimately determined that there was no change, and thus no

submission to the Office is needed. Accordingly, analyzing the attributable owner status also imposes a burden on the applicant and patentee. This additional burden is not included in the Office's burden estimate.

b. It Will Pose an Undue Burden to Report Attributable Owner Prior to Payment of Each Maintenance Fee

It will also pose an undue burden to require submission of attributable owner information prior to the payment of the maintenance fee. Like many large corporations, GSK uses an annuity payment service provider to pay its maintenance fees. GSK formalities group supplies a report to the annuity payment service provider, who then pays the maintenance fees. GSK is not informed of the exact date the maintenance fee will be paid, but instead are informed that it will be paid in a given window. Patent attorneys are not involved in the process. If GSK is required to submit attributable owner information prior to the payment of the maintenance fee, GSK will need to implement processes that will pose an undue burden, for example, new docketing procedures will need to be implemented to alert the attorney to perform an attributable ownership investigation. The attorney will need to ascertain whether any transfers of rights have occurred, analyze transactions that have occurred, determine whether a reportable change has occurred, and ensure that the investigation concludes in time to be able to pay the maintenance fee on time. The patent attorney, the paralegal, formalities, and the annuity payment service provider will need to coordinate the attributable owner submission prior to payment of the maintenance fee. *GSK believes this would be an undue burden, particularly if required to be performed for every unexpired US patent in its portfolio on which a maintenance fee is due.*

VI. Recommended Procedure For Identifying the Titleholder

GSK believes that the titleholder can be identified on the Application Data Sheet.

GSK notes that the Patent Term Adjustment rules may need to be revised to accommodate the filing of an Application Data Sheet after Notice of Allowance. For example, under 37 C.F.R. 1.704(c)(10), submission of an amendment under section 1.312 or other paper after notice of allowance has been given or mailed will result in reduction of patent term adjustment. The Office has interpreted an Application Data Sheet to be an "other paper" under the rules.

VII. Information Required to Identify a Corporate Titleholder

GSK believes it is adequate to identify the name of the legal entity and the registered place of business (e.g., city and state of incorporation).

VIII. The Penalty for Non-Compliance Is Unclear In Some Instances

a. In Regard to Reporting Changes During Prosecution

Proposed Section 1.275 indicates that an applicant has three months from the date of the change to the attributable owner within which to file a notice identifying the current attributable owner. The section indicates that the three-month period is not extendable. The section fails to indicate the penalty for not complying with this requirement. Indeed, it seems that the Office cannot implement a penalty as the Office will be unaware that there has been a change in the attributable owner, and thus unaware that the three month deadline has been missed.

It seems that this requirement will possibly be a fertile ground for costly inequitable conduct litigation, that could include: (1) determining the entire attributable ownership picture for the patent application during prosecution, which may involve analysis of numerous intra-company agreements accompanied by a determination of which entities should have been considered attributable owners under the rules; (2) determining whether there was any change in attributable ownership during the pendency; (3) if there was a change, determining why the change was not identified to the Office – was the patent attorney aware of the change; if not, should he have been aware of it; etc.

b. In Regard to Payment of a Maintenance Fee

Section 1.381 provides no penalty for failing to identify the current attributable owner(s) with maintenance fee payment. GSK believes this is a reasonable approach, and that the PTO should defer to Congress and pending legislation to provide consequences for failure to disclose ownership information attendant to litigation. It is also questionable whether the USPTO has the power to impose such requirements on issued patents.

GSK appreciates the opportunity to submit comments on the Changes to Require Identification of Attributable Owner published in the Federal Register on January 24, 2014 and hopes that comments like these from the user community will assist the Office in aligning any benefits that can be gained by implementing the rules with the cost of doing so.

Best regards,



J. Michael Strickland

Assistant General Counsel (Patents)
GlaxoSmithKline